DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

December 14, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 01-12

Mark Clemens, Regional President
Airgas Norpac
3591 North Columbia Blvd.
Portland, Oregon 97217

WARNING LETTER

Dear Mr. Clemens:

A Food and Drug Administration (FDA) inspection was conducted on October 27 and 30, 2000, at your liquid oxygen transfilling facility located at 2043 S. 35th Street, Tacoma, Washington. Medical gases are drug products as defined by Section 201(g) of the Federal, Food, Drug, and Cosmetic Act (the Act).

During our inspection, deviations from the Current Good Manufacturing Practice (GMP) requirements (Title 21, Code of Federal Regulations (CFR), Part 211) were observed. These deviations cause your medical gases to be adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for, their manufacturing, processing, packing, storage, or holding, are not in conformance with the GMP regulations.

The deviations included the following:

- Failure to have written procedures describing specific responsibilities and authorities of the quality control unit (QCU).

- Failure to have written procedures easily accessible to employees working at the high-pressure oxygen fill line and the liquid oxygen fill area.

- Failure to have written procedures that are "reviewed and approved by the local and/or corporate QCU" for the line personnel working at the high-pressure oxygen fill line and liquid oxygen fill area.

- Failure to have the analytical method used to determine the strength and identity of oxygen USP on the certificate of analysis for the [redacted] calibration standard.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations at your facility. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the

The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine the causes to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters concerning drug products so that they may take this information into account when awarding contracts. By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice. These actions, include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Seattle District Office, 22201 23rd Drive SE, Bothell, Washington, 98021-4421, to the attention of Lisa M. Elrand, Compliance Officer. Ms. Elrand can be reached at (425) 483-4913.

Sincerely,

/Kristy D. Davis/
for Charles M. Breen
District Director

Enclosure:
FDA 483